DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 25, 2015

Jiangsu BaiDe Medical Instrument Co., Ltd.
% Ms. Alice Gong
Shanghai Yarui Consultant Co., Ltd.
503 Room, 8 Building, 600 Liu Zhou Road
Shanghai, Shanghai 200233
China

Re: K150009
Trade/Device Name: Baide®
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: November 18, 2014
Received: January 2, 2015

Dear Ms. Alice Gong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K150009

Device Name
Trade name: BaiDe®
Common name: Locking Plate System

Indications for Use *(Describe)*
BaiDe® locking plate system is intended for adult patients as indicated for fixation of fractures of tibia.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**Section 5 of Traditional 510(K) Submission:**

**510 (K) Summary**

**This 510(K) Summary of safety and effectiveness information is being submitted in accordance with requirement of 21 CFR807.92**

**1.** Date of Submission: Nov. 18, 2014
**2.** Submitter / 510(K) Holder

Jiangsu BaiDe Medical Instrument Co.,Ltd.
South Side of Dongqi Road, Donglai Village, YangShe Town
Zhangjiagang City
Jiangsu Province
China

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**3.** Proposed Device Namet

Trade name: BaiDe®
Common name: Locking Plate System

Classification Name: Plate, Fixation, Bone
Device Class: Class II
Classification Panel: Orthopedic Panel
Product Code: HRS
Regulation Number: 21 CFR 888.3030

Classification Name: Screw, Fixation, Bone
Device Class: Class II
Classification Panel: Orthopedic Panel
Product Code: HWC
Regulation Number: 21 CFR 888.3040

**4.** Predicate Devices

**Predicate Devices #1:**

510 (k) Number: K133840
Product Name: Locking Bone Plates and Scews
Submitter: Suzhou Kangli Orthopaedic Instrument Co., Ltd.

**Predicate Devices #2:**
510 (k) Number: K130340
Product Name: Locking Bone Plates and Scews
Submitter: Weigao Orthopaedic Device Co., Ltd.

## 5. Device Description

BaiDe® locking plate system contains locking plates with various specifications, metal bone and locking screws with various specifications, and various specific instruments. The bone plates are used for fixation of bones. The screws are used for fix the plates on the bones and the instruments are used for completing the surgery.

The bone plates are manufactured from unalloyed titanium that conforms to ASTM F67. The metal bone and locking screws are made of Ti6Al4V ELI that meets to ASTM F136. The materials of titanium and Ti6Al4V ELI are widely used in the industry with well-known biocompatibility. No new materials are used in the development of this implant.

## 6. Indication for Use/Intended Use

BaiDe® locking plate system is intended for adult patients as indicated for fixation of fractures of tibia.

## 7. Non-Clinical Testing

Bench tests were conducted to verify that proposed device meet all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that proposed device complies with the following standards:

ASTM F 382-99 (Reapproved 2008), Standard Specification and Test Method for Metallic Bone Plates, including the following items:
* Static four point bending
* Dynamic four point bending

ASTM F 543-07, Standard Specification and Test Methods for Metallic Medical Bone Screws including the following item:
* Torsional properties
* Driving torque
* Pull out test

## 8. Substantially Equivalent Conclusion

The BaiDe® locking plate system has same intended use as the predicate device and similar technological characteristics as the predicate device. The proposed device, the BaiDe® locking plate system, is determined to be Substantially Equivalent (SE) to the predicate device, K133840 Kangli® locking plate system and K130340 locking bone plates and screws, in respect of safety and effectiveness.